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111 MONUMENT CIRCLE, SUITE 3700
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EXAMINER	
LLOYD, EMILY M	

ART UNIT	PAPER NUMBER
3736	

NOTIFICATION DATE	DELIVERY MODE
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/767,522	ROE ET AL.	
	Examiner	Art Unit	
	Emily M. Lloyd	3736	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-54* is/are pending in the application.

4a) Of the above claim(s) *18,25,26,28-31,38-46 and 49* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17,19-24,27,32-37,47,48 and 50-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :02/13/2004,10/04/2004,06/26/2006,06/06/2007.

DETAILED ACTION

Election/Restrictions

1. Applicant's election without traverse of Species I in the reply filed on 6 June 2007 is acknowledged.

2. Claims 18, 25-26, 28-31, 38-46, and 49 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 6 June 2007.

Information Disclosure Statement

3. The information disclosure statement filed 6 June 2007 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered.

Specification

4. The disclosure is objected to because of the following informalities: page 5 lines 11 and 13, page 11 line 2, and any other occurrences of the word "cite" for a location should be changed to "site"; page 9 line 18 the word "to" should be added after "have"; page 9 line 25 the word "to" should be added after "due"; page 9 line 26 the word "film" should be added after "hydrophilic"; page 9 line 28 the word "that" should be added after "such"; page 10 line 16 the word "be" should be added before "formed"; page 10 line 16 one of the phrases "may reduce" should be deleted from the end of the line; page 10

line 18 the word "a" should be added after "includes"; page 10 line 24 the word "form" should be changed to "from"; and page 11 line 10 the word "is" should be changed to "are".

Appropriate correction is required.

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Objections

6. Claims 10 and 33 are objected to because of the following informalities: claim 10 line 5 the word "the" should be added before the word "base"; and claim 33 should have a period added at the end. Appropriate correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claims 1, 32, and 33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claims 1, 32, and 33 cite "extends/extending from the housing proximal the opening of the capillary channel" which should be revised for clarity. For the purpose of examination, the Examiner has interpreted this as meaning that the component claimed both extends distally from the housing and also

has a portion of the component that is attached to the housing proximal the opening of the capillary channel.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 1, 3, 6-7, 9-10, 14-17, 19-24, 27, and 32-37 are rejected under 35 U.S.C. 102(b) as being anticipated by United States Patent 6143164 (Heller et al.).

Regarding claim 1, Heller et al. disclose a device for sampling a bodily fluid from an incision in skin, comprising: a lancet (skin piercing member 54 Figure 6, Column 12 lines 2-3) to form the incision in the skin; a housing (Figure 6) coupled to the lancet, the housing defining at least in part a capillary channel (sample chamber 26 Figure 5) with an opening (distal end of sample chamber 26 Figure 5), the capillary channel being sized to draw the bodily fluid from the incision via capillary action; and a flexible sheet (sorbent material 34 Figure 5 and tab 33) extending from the housing proximal the opening of the capillary channel to draw the bodily fluid into the opening of the capillary channel (Column 11 lines 11-26).

Regarding claim 3, Heller et al. disclose the device of claim 1, wherein the sheet is hydrophilic (cellulose is hydrophilic Column 10 line 59) for enhancing the flow rate of the bodily fluid into the capillary channel.

Regarding claim 6, Heller et al. disclose the device of claim 1, wherein the sheet is transparent (Column 10 lines 58-60, nylon and polyethylene are at least partially transparent as evidenced by United States Patent 5582184 (Erickson et al.) Column 6 lines 18-20, and a cellulose derivative is transparent as evidenced by United States Patent 4095589 (Manschot et al.) Column 2 lines 6-7) for allowing a user to view the bodily fluid while being drawn into the capillary channel.

Regarding claim 7, Heller et al. disclose the device of claim 1, wherein: the housing has an outside surface (Figure 6); and the lancet is attached to the outside surface of the housing (Column 11 line 63-Column 12 line 5).

Regarding claim 9, Heller et al. disclose the device of claim 1, wherein the housing defines a registration opening for positioning the housing (hole in proximal end, Figures 5 and 6).

Regarding claim 10, Heller et al. disclose the device of claim 1, wherein: the housing includes a base and a spacer member attached to the base (plate 38 Figure 3); the spacer member defines a slot (slot in the middle of spacer 28 Figure 3); the sheet covers at least a portion of the slot (Figure 5, also Column 17 lines 48-50 sorbent material (sheet) is between "working electrode 42 and its corresponding counter electrode", Column 17 lines 32-35 the counter electrodes on are another sheet); and the spacer member is sandwiched between base and the sheet to form the capillary channel in the slot (Column 17 lines 48-50 sorbent material (sheet) is between "working electrode 42 and its corresponding counter electrode", Column 17 lines 32-35 the

counter electrodes on are another sheet, so the spacer member is sandwiched between the sorbent material (sheet) above it and the base below it).

Regarding claim 14, Heller et al. disclose the device of claim 10, further comprising a test area positioned along the capillary channel for analyzing the bodily fluid (electrode 42 Figure 5).

Regarding claim 15, Heller et al. disclose the device of claim 1, wherein the lancet includes a lancet tip that extends from the housing past the opening of the capillary channel to form the incision (Figure 6 and Column 12 lines 2-5, the lancet tip would have to extend past the opening of the capillary channel in order to be injected into a patient's skin).

Regarding claim 16, Heller et al. disclose the device of claim 15, wherein the lancet tip has a triangular shape (distal end of skin piercing member 54 Figure 6).

Regarding claim 17, Heller et al. disclose the device of claim 15, wherein the lancet tip has a slanted shape (distal end of skin piercing member 54 Figure 6).

Regarding claim 19, Heller et al. disclose the device of claim 15, wherein the sheet extends past the lancet tip in order for the sheet to remain in contact with the skin and draw the bodily fluid when the lancet tip is removed from the skin (tab 33 and Column 11 lines 11-27).

Regarding claim 20, Heller et al. disclose the device of claim 1, wherein the housing and the lancet are flat (electrochemical sensor 20 Figure 6 is flat and skin piercing member 54 Figure 6 is flat).

Regarding claim 21, Heller et al. disclose the device of claim 1, further comprising means for testing the bodily fluid (electrode 42 Figure 5) in the capillary channel.

Regarding claim 22, Heller et al. disclose the device of claim 21, wherein the means for testing the bodily fluid includes a reagent test strip (Column 17 lines 45-48).

Regarding claim 23, Heller et al. disclose the device of claim 1, further comprising a testing system (electrode 42 Figure 5) positioned along the capillary channel to analyze the bodily fluid.

Regarding claim 24, Heller et al. disclose the device of claim 23, wherein the testing system includes a reagent test strip (Column 17 lines 45-48).

Regarding claim 27, Heller et al. disclose the device of claim 23, wherein: the sheet is hydrophilic (cellulose is hydrophilic Column 10 line 59); and the sheet extends along the capillary channel to draw the bodily fluid onto the test system (sorbent material 34 in sample chamber 26 Figure 5).

Regarding claim 32, Heller et al. disclose a method of sampling a bodily fluid from an incision in skin, comprising: providing a device that includes a housing (Figure 6) that defines a capillary channel (sample chamber 26 Figure 5) with an opening (distal end of sample chamber 26 Figure 5), a lancet (skin piercing member 54 Figure 6, Column 11 line 63-Column 12 line 3) coupled to the housing, and a flexible sheet (sorbent material 34 Figure 5 with tab 33 Column 11 lines 11-26) that extends from the housing proximal the opening of the capillary channel; lancing the incision in the skin

with the lancet (Column 12 lines 1-5); and drawing the bodily fluid from the incision into the capillary channel with the sheet (Column 12 lines 6-10).

Regarding claim 33, Heller et al. disclose the method of claim 32, wherein: the lancet includes a lancet tip extending from the housing proximal the opening of the capillary channel (Figure 6 and Column 12 lines 2-5, the lancet tip would have to extend past the opening of the capillary channel in order to be injected into a patient's skin); and said drawing includes retracting the lancet tip (Column 12 lines 6-7) from the skin to a position with the sheet remaining in contact with the skin (Column 12 lines 7-10).

Regarding claim 34, Heller et al. disclose the method of claim 33, further comprising: wherein the device includes testing means (electrode 42 Figure 5) positioned along the capillary channel; depositing the bodily fluid in the capillary channel onto the testing means (Column 18 lines 18-26 and Column 19 lines 61-62); and analyzing the bodily fluid with the testing means (Column 19 line 63-Column 20 line 12, Column 20 lines 20-21, Table 1, and Figure 7).

Regarding claim 35, Heller et al. disclose the method of claim 34, wherein said analyzing includes chemically testing analyte levels in the bodily fluid (Column 20 line 5).

Regarding claim 36, Heller et al. disclose the method of claim 34, wherein said analyzing includes electrochemically testing analyte level in the bodily fluid (Column 20 line 5).

Regarding claim 37, Heller et al. disclose the method of claim 32, further comprising: wherein the device includes testing means (electrode 42 Figure 5)

positioned along the capillary channel; depositing the bodily fluid in the capillary channel onto the testing means (Column 18 lines 18-26 and Column 19 lines 61-62); and analyzing the bodily fluid with the testing means (Column 19 line 63-Column 20 line 12, Column 20 lines 20-21, Table 1, and Figure 7).

11. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

12. Claims 47-48 and 51-54 are rejected under 35 U.S.C. 102(e) as being anticipated by United States Patent Publication 2003/0028087 (Yuzhakov et al.).

Regarding claim 47, Yuzhakov et al. disclose an integrated bodily fluid sampling device for sampling a bodily fluid from an incision in skin, comprising: a housing (test strip 20 Figure 3) defining a capillary channel (fluid pathways 24 Figure 3) with an opening configured to draw the bodily fluid via capillary action; a lancet (skin piercing elements 22 Figure 3) having a lancet tip for forming the incision in the skin, the lancet being attached to the housing with the lancet tip extending from around the opening of the channel, the lancet being immovable with respect to the housing ([0069] lines 5-8); and means for testing the bodily fluid positioned along the channel (reaction area 14 Figure 3).

Regarding claim 48, Yuzhakov et al. disclose the device of claim 47, wherein the means for testing the bodily fluid includes a chemical reagent test strip (reagent 16 is part of reaction area 14, Figure 3).

Regarding claim 51, Yuzhakov et al. disclose the device of claim 47, wherein the lancet has a flat shape (microneedles 44 and 48 Figures 5A and 5B).

Regarding claim 52, Yuzhakov et al. disclose the device of claim 47, wherein the housing includes: a base (support material 6 Figure 3); a cover (support material 8 Figure 3); and a spacer (spacer layer 12 Figure 3) sandwiched between the base and the cover to define the channel.

Regarding claim 53, Yuzhakov et al. disclose the device of claim 52, wherein the lancet, the base, the cover and the lancet have an overall flat shape (Figure 3).

Regarding claim 54, Yuzhakov et al. disclose the device of claim 47, wherein the housing defines a notch at the opening of the channel for minimizing dose hesitation of the bodily fluid into the opening (notch defined by sets of micro-needles 44, 48 and spacer layer 50 Figures 5A and 5B).

Claim Rejections - 35 USC § 103

13. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

14. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

15. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

16. Claim 50 is rejected under 35 U.S.C. 103(a) as being unpatentable over Yuzhakov et al. in view of Heller et al.

Regarding claim 50, Yuzhakov et al. disclose the device of claim 47 (see 102(e) rejection of claim 47 above). Yuzhakov et al. do not disclose a sheet of hydrophilic film extending from the opening of the channel for drawing the bodily fluid into the channel. Heller et al. teach the use of a sheet of hydrophilic film extending from the opening of the channel for drawing the bodily fluid into the channel (Column 11 lines 11-26). It would have been obvious to one having ordinary skill in the art at the time the invention

was made to use such a sheet of hydrophilic film extending from the opening of the channel for drawing the bodily fluid into the channel as taught by Heller et al. in the invention of Yuzhakov et al. because this would further assist with the wicking in Yuzhakov et al.'s invention (Yuzhakov et al. [0070] lines 14-20, Heller et al. Column 11 lines 11-16).

17. Claims 2 and 11-13 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. in view of WO 00/19185 (Miltner et al.). References to Miltner et al. are to the English translation of WO 00/19185 (United States Patent 6707554).

Regarding claim 2, Heller et al. disclose the device of claim 1 (see 102(b) rejection of claim 1 above). Heller et al. do not disclose that the housing defines a notch at the opening of the capillary channel to minimize dose hesitation of the bodily fluid into the capillary channel. Miltner et al. teach the use of the housing defining a notch at the opening of the capillary channel to minimize dose hesitation of the bodily fluid into the capillary channel (opening 5 Figure 1A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a housing that defines a notch at the opening of the capillary channel to minimize dose hesitation of the bodily fluid into the capillary channel as taught by Miltner et al. in the invention of Heller et al. because both devices have openings to collect blood in a capillary channel (Miltner et al. Column 7 lines 56-62, Heller et al. Column 11 lines 34-36).

Regarding claim 11, Heller et al. disclose the device of claim 10 (see 102(b) rejection of claim 10 above), wherein the housing includes a cover covering the sheet over the slot (Heller et al. plate 38 Figure 3). Heller et al. do not disclose a vent

member defining a vent opening for exhausting gas from the capillary channel. Miltner et al. teach a vent member (portion of cover foil 3 proximal reagent paper 6, Figures 1A and 1B) defining a vent opening for exhausting gas from the capillary channel (opening in capillary gap 7 proximal reagent paper 6, Figure 1A). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a vent member defining a vent opening for exhausting gas from the capillary channel as taught by Miltner et al. in the invention of Heller et al. because this would prevent air from being trapped inside the capillary channel that would make it more difficult for the blood to reach all of the electrodes and it was well known to one of ordinary skill in the art at the time the invention was made to use such a vent member in a test strip.

Regarding claim 12, Heller et al. as modified by Miltner et al. disclose the device of claim 11, further comprising a test area positioned along the capillary channel in which the bodily fluid is analyzed (Heller et al. electrode 42 Figure 5), wherein the vent opening (Miltner et al. opening in capillary gap 7 proximal reagent paper 6, Figure 1A) is defined between the test area (Miltner et al. detection zone 10 Figure 1A) and the vent member (Miltner et al. portion of cover foil 3 proximal reagent paper 6, Figure 1A).

Regarding claim 13, Heller et al. as modified by Miltner et al. disclose the device of claim 12, wherein the test area includes a reagent test strip (Heller et al. Column 17 lines 45-48).

18. Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. in view of United States Patent Publication 2001/0027277 (Klitmose).

Regarding claim 8, Heller et al. disclose the device of claim 7 (see 102(b) rejection of claim 7 above). Heller et al. do not disclose that the lancet is glued to the outside surface of the housing. Klitmose teaches the use of gluing the lancet to the outside surface of the housing ([0042] lines 1-2). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a lancet glued to the outside surface of the housing as taught by Klitmose in the invention of Heller et al. because this would minimize the number of items a patient would have to carry (Klitmose [0007] lines 1-5) and would easily ensure that the patient has enough reagent carrying strips and lancets (Klitmose [0005] lines 3-12 and [0010] lines 5-7).

19. Claims 4 and 5 are rejected under 35 U.S.C. 103(a) as being unpatentable over Heller et al. in view of United States Patent 6045497 (Schweich, Jr. et al.).

Regarding claim 4, Heller et al. disclose the device of claim 3 (see 102(b) rejection of claim 3 above). Heller et al. do not disclose that the sheet is coated with a hydrophilic coating. Schweich, Jr. et al. teach the use of a hydrophilic coating (Column 11 lines 48-49). It would have been obvious to one having ordinary skill in the art at the time the invention was made to use such a hydrophilic coating as taught by Schweich, Jr. et al. in the invention of Heller et al. because this could provide cost savings in the invention of Heller et al.'s sorbent material.

Regarding claim 5, Heller et al. as modified by Schweich, Jr. et al. disclose the device of claim 4, wherein the hydrophilic coating includes aluminum oxide (Schweich, Jr. et al. Column 11 lines 57-59).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Emily M. Lloyd whose telephone number is 571-272-2951. The examiner can normally be reached on Monday through Friday 8:30 AM - 5 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Max Hindenburg can be reached on 571-272-4726. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Emily M Lloyd
Examiner
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/EML/